

## REMARKS

This Amendment is in response to the Examiner's Official Action mailed October 3, 2003. Claim 9 is amended. Claims 1-30 are now pending.

### **I. Obviousness-Type Double Patenting Rejection over the '830 Patent**

Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent No: 6,482,830 (the '830 patent). Specifically, the Examiner states that the claims of the '830 patent and the Application overlap, in that the patent claims an exotherm between 272 and 274 (see claim 1), and the Application claims an exotherm of between 273.6 and 275.6 (see claim 1).

Applicants disagree with the Examiner that the claimed invention is not patentably distinct from the '830 patent. Claim 1 of the Application specifies a polymorphic form of 9-nitrocamptothecin (9NC). The crystal form of 9NC has the following distinct spectral characteristics as recited in claim 1:

- 1) by differential scanning calorimetry, no observable endotherm and an exotherm at between 273.6 and 275.6°C; and
- 2) a solution NMR spectrum with multiplets at 1.7 and 3.7 ppm shifts.

In contrast, the crystal form of 9NC disclosed in the '830 patent is in a different form having the following spectral characteristics as recited in claim 1 of the patent: an endotherm at between 149.2 and 151.2°C, an exotherm at between 162.6 and 164.6°C, and an exotherm at between 272 and 274°C.

As shown above, the claimed crystal form of 9NC of the Application does not have an observable endotherm whereas the crystal form in the '830 patent has an endotherm at between 149.2 and 151.2°C. These two crystal forms of 9NC are distinctly different from each other and non-obvious in view of each other.

However, to expedite the prosecution, Applicants submit herewith a terminal disclaimer over the '830 patent. Withdrawal of the rejection is therefore respectfully requested.

## **II. Obviousness-Type Double Patenting Rejection over the '003 Application**

Claims 1-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of co-pending Application No. 10/082,003 (the '003 application). The reason for the Examiner's rejection is merely because the instant application and the '003 application are claiming a common subject matter: a polymorphic form of 9NC.

Applicants disagree with the Examiner that the claimed invention is not patentably distinct from the '003 application. As discussed above, claim 1 of the instant application specifies a polymorphic form of 9NC having the following distinct spectral characteristics:

- 1) by differential scanning calorimetry, no observable endotherm and an exotherm at between 273.6 and 275.6°C; and
- 2) a solution NMR spectrum with multiplets at 1.7 and 3.7 ppm shifts.

In contrast, the crystal form of 9NC disclosed in the '003 applications is in a different form having the following spectral characteristics as recited in claim 1 of the referenced application: an endotherm at between 273.9 to 275.9°C, and an exotherm at between 279.3 and 281.3°C.

As shown above, the claimed crystal form of 9NC of the instant application does not have an observable endotherm whereas the crystal form claimed in the '003 application has an endotherm at between 273.9 to 275.9°C, and the exotherm range does not overlap with that of the claimed crystal form of 9NC. These two crystal forms of 9NC are distinctly different from each other and non-obvious in view of each other.


However, to expedite the prosecution, Applicants submit herewith a terminal disclaimer over the '003 application. Withdrawal of the rejection is therefore respectfully requested.

## CONCLUSION

In view of the above amendment and remarks, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

Date: Dec. 23, 2003

By:   
Shirley Chen, Ph.D.  
Reg. No. 44,608

WILSON SONSINI GOODRICH & ROSATI  
650 Page Mill Road  
Palo Alto, CA 94304-1505  
Direct Line: (650) 565-3856  
Client No. 021971